AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-146 (cancelled)

Claim 147. (New): A pharmaceutical excipient comprising a solid, reticulated matrix, wherein the matrix comprises an aggregation of inorganic particles in association with an organic polymeric material, defines a plurality of pores with a mean width in the range of about 0.01-500μm, and has a specific surface area of at least about 1 m^2/g.

Claim 148. (New): An excipient as claimed in claim 147, wherein:

(a) the pores have a mean width in the range of about 0.1-500μm and the matrix has a specific surface area of no more than about $100m^2/g$;

(b) the mean width of the pores is in a range of about 0.5-300, 1-200, 3-100, 5-80, 15-70, 20-60 or 0.1-10μm;

(c) the matrix has a specific surface area of at least about 2, 3, 4, 5, 10 or 20 m^2/g, and/or up to about 100, 50 or $40m^2/g$;

(d) the inorganic particles are crystalline;

(e) the aggregation of inorganic particles comprises a plurality of discrete crystals; and/or,

(f) the mean width of the inorganic particles is about 0.1-50μm.

Claim 149. (New): An excipient as claimed in claim 147, wherein the pores comprise primary and secondary pores, the primary pores have a mean width of about 2-500μm and are defined between structural elements formed from the matrix, the secondary pores have a mean width of 0.01–10μm and are defined within said structural elements, and the mean width of the secondary pores is less than the mean width of the primary pores.

Claim 150. (New): A pharmaceutical excipient comprising a solid, reticulated matrix, wherein the matrix comprises an inorganic material in association with an organic polymeric material, a

plurality of primary pores with a mean width of about 2-500μm are defined between structural elements formed from the matrix, a plurality of secondary pores with a mean width of about 0.01-10μm are defined within said structural elements, and the mean width of the secondary pores is less than the mean width of the primary pores.

Claim 151. (New): An excipient as claimed in claim 150, wherein:

(a) the matrix has a specific surface area of at least 0.1, 0.5, 1, 3, 4, 5, 10 m^2/g, and/or up to about 100, 50 or 40m^2/g;

(b) the mean width of the primary pores is at least about 5, 10, 20 or 40μm, and/or no more than about 300, 200, 100 or 50μm;

(c) the mean width of the secondary pores is at least about 0.01, 0.05, or 0,1μm, and/or no more than about 5, 3, 2, 1.5 or 1μm; and/or,

(d) at least about 50, 55, 70, 80, 90, or 95% of the primary pores have a width that is greater than the mean width of the secondary pores, and/or at least about 50, 55, 70, 80, 90, or 95% of the secondary pores have a width that is less than the mean width of the primary pores.

Claim 152. (New): An excipient as claimed in claim 149, wherein the structural elements form primary walls that define the primary pores, and comprise a network of secondary walls that define the secondary pores.

Claim 153. (New): An excipient as claimed in claim 150, wherein the structural elements form primary walls that define the primary pores, and comprise a network of secondary walls that define the secondary pores.

Claim 154. (New): An excipient as claimed in claim 147, wherein the matrix is in the form of a plurality of agglomerations of organic polymeric material and inorganic particles or material, in which the secondary pores are formed, and the primary pores are preferably located between adjacent agglomerations.

Claim 155. (New): An excipient as claimed in claim 150, wherein the matrix is in the form of a plurality of agglomerations of organic polymeric material and inorganic particles or material, in which the secondary pores are formed, and the primary pores are preferably located between adjacent agglomerations.

Claim 156. (New): An excipient as claimed in claim 149, wherein the inorganic material is particulate, preferably crystalline and, optionally, comprises a plurality of discrete crystals.

Claim 157. (New): An excipient as claimed in claim 150, wherein the inorganic material is particulate, preferably crystalline and, optionally, comprises a plurality of discrete crystals.

Claim 158. (New): An excipient as claimed in claim 149, wherein the mean width of the organic particles is within the range of about 0.1-50μm.

Claim 159. (New): An excipient as claimed in claim 150, wherein the mean width of the organic particles is within the range of about 0.1-50μm.

Claim 160. (New):An excipient as claimed in claim 147, wherein:

(a) the organic polymeric material binds the inorganic particles or material into the matrix;

(b) the organic polymeric material forms a template for the inorganic particles or material;

(c) the matrix consists essentially or solely of an aggregation of inorganic particles in association with an organic polymeric material;

(d) the organic polymeric material is at least readily soluble in water at a temperature of between 20 and 50°C within a period of 24 hours;

(e) the polymeric material comprises a polysaccharide and/or a protein; and/or,

(f) the polymeric material comprises xanthan gum, dextran, acacia gum and/or egg albumen.

Claim 161. (New): An excipient as claimed in claim 150, wherein:

(a) the organic polymeric material binds the inorganic particles or material into the matrix;

(b) the organic polymeric material forms a template for the inorganic particles or material;

(c) the matrix consists essentially or solely of an aggregation of inorganic particles in association with an organic polymeric material;

(d) the organic polymeric material is at least readily soluble in water at a temperature of between 20 and 50°C within a period of 24 hours;

(e) the polymeric material comprises a polysaccharide and/or a protein; and/or,

(f) the polymeric material comprises xanthan gum, dextran, acacia gum and/or egg albumen.

Claim 162. (New): An excipient as claimed in claim 147 consisting essentially or solely of the matrix, and/or comprising from about 5 to about 95% by weight of said polymeric material or template.

Claim 163. (New): An excipient as claimed in claim 150 consisting essentially or solely of the matrix, and/or comprising from about 5 to about 95% by weight of said polymeric material or template.

Claim 164. (New): A pharmaceutical excipient comprising a porous network of fused inorganic elements, said network defining a plurality of pores with a mean width within the range of about 0.01-100μm.

Claim 165. (New):An excipient as claimed in claim 18, wherein the inorganic elements have a mean width of no more than about 10, 5 or 2μm, and/or are at least partially crystalline.

Claim 166. (New): An excipient as claimed in claim 164, wherein the pores comprise primary and secondary pores, the primary pores have a mean width of about 2-500μm and are defined between structural elements formed from the matrix, the secondary pores have a mean width of 0.01-10μm and are defined within said structural elements, and the mean width of the secondary pores is less than the mean width of the primary pores.

Claim 167. (New): An excipient as claimed in claim 166, wherein:

(a) the mean width of the primary pores is at least about 5, 10, 20 or 40μm, and/or no more than about 300, 200, 100 or 50μm;

(b) the mean width of the secondary pores is at least about 0.01, 0.05, or 0.1μm and/or no more than about 5, 3, 2, 1.5 or 1μm; and/or,

(c) at least about 50, 55, 70, 80, 90, or 95% of the primary pores have a width that is greater than the mean width of the secondary pores and/or at least about 50, 55, 70, 80, 90, or 95% of the secondary pores have a width that is less than the mean width of the primary pores.

Claim 168. (New): An excipient as claimed in claim 166, wherein the structural elements form primary walls that define the primary pores, and comprise a network of secondary walls that define the secondary pores.

Claim 169. (New): An excipient as claimed in claim 168, wherein the primary walls have a mean width of about 10-500, 10-200, 20-100 or 10-50μm, and/or the secondary walls have a mean width of about 0.01-5 or 0.5-2μm.

Claim 170. (New): An excipient as claimed in claim 164 comprising a plurality of pores with a mean width of 0.01-50μm.

Claim 171. (New): An excipient as claimed in claim 164 consisting essentially or solely of said fused inorganic elements.

Claim 172. (New): An excipient as claimed in claim 147, wherein the inorganic material comprises or the inorganic particles comprise silica and/or a pharmaceutical acceptable alkaline earth metal salt, preferably calcium phosphate and/or calcium carbonate.

Claim 173. (New): An excipient as claimed in claim 150, wherein the inorganic material comprises or the inorganic particles comprise silica and/or a pharmaceutical acceptable alkaline earth metal salt, preferably calcium phosphate and/or calcium carbonate.

Claim 174. (New):An excipient as claimed in claim 164, wherein the inorganic material comprises or the inorganic particles comprise silica and/or a pharmaceutical acceptable alkaline earth metal salt, preferably calcium phosphate and/or calcium carbonate.

Claim 175. (New):A method of preparing a solid, reticulated matrix including the steps of, forming a reticulated template comprising an organic polymeric material, forming a construct comprising an aggregation of inorganic particles in association with said template, and solidifying said construct to form a solid, reticulated matrix comprising the inorganic particles in association with the organic polymeric material, where said matrix defines a plurality of pores with a mean width of 0.01-500μm and/or has a specific density of at least $1m^2/g$.

Claim 176. (New):A method as claimed in claim 175, wherein:

(a) the reticulated template, aggregation of inorganic particles and the construct are formed substantially simultaneously; and/or,

(b) the reticulated template is formed by dispersing a second phase in a liquid phase that comprises the organic polymeric material.

Claim 177. (New): A method as claimed in claim 176, wherein said second phase comprises or consists essentially of solid particles and/or gas bubbles, and/or the liquid phase comprises a solution of the organic polymeric material.

Claim 178. (New): A method as claimed in claim 177, wherein the solid particles are soluble in a solvent in which the organic polymeric material, once set or solidified, is substantially insoluble and the inorganic particles, preferably, are substantially insoluble in said solvent.

Claim 179. (New): A method as claimed in claim 175, wherein:

(a) the reticulated template is spontaneously formed from a solution of organic polymeric material, or by the action of a cross-linking agent on a dissolved organic polymeric material;

(b) the reticulated template is formed from an aqueous solution of the polymeric material; and/or,

(c) a proportion of the inorganic particles are formed by precipitation from a solution comprising the organic polymeric material and, preferably, the inorganic particles comprise an inorganic salt and said solution further comprises dissolved anions and/or cations of said salt.

Claim 180. (New): A method as claimed in claim 179(c), wherein, before precipitation is initiated, said solution includes dissolved anions but substantially no dissolved cations, or dissolved cations and substantially no dissolved anions of the salt, and precipitation, preferably, is caused by the addition of a solution comprising the counter ions required to form the salt.

Claim 181. (New):A method as claimed in claim 179(c), wherein formation of the inorganic particles by precipitation can take place during or after the formation of the reticulated template.

Claim 182. (New): A method as claimed in claim 175, wherein at least a proportion of and, optionally, substantially all of the inorganic particles are pre-formed and dispersed in a liquid phase which comprises the organic polymeric material, or substantially all of the inorganic particles are formed by precipitation from a solution comprising the organic polymeric material.

Claim 183. (New):A method as claimed in claim 175, wherein:

(a) the inorganic particles are crystalline;

(b) the mean width of the particles or crystals of inorganic material is in the range of about 0.1-50μm;

(c) the aggregation of inorganic particles forms a part of the reticulated template; and/or,

(d) the construct of reticulated template and aggregation of inorganic particles is solidified by air-drying, spontaneous cross-linking, the action of a cross-linking agent, the effect of a temperature change, the act of forming the inorganic particles by precipitation and/or the influence of electro-magnetic radiation.

Claim 184. (New): A method as claimed in claim 175, wherein the reticulated template is formed by entraining gas bubbles in a liquid phase comprising the organic polymeric material, and at least a proportion of the inorganic particles are caused to precipitate during said entrainment process, or the reticulated structure is formed by distributing solid particles in a liquid phase comprising the organic polymeric material and the solid particles are removed after the construct has been solidified by dissolution in an appropriate solvent.

Claim 185. (New): A method as claimed in claim 184, wherein the liquid phase comprises a solution of the organic polymeric material.

Claim 186. (New):A method as claimed in claim 175, wherein the organic polymeric material includes or is a polysaccharide and/or a protein, and/or the inorganic particles comprise an alkaline earth metal carbonate and/or phosphate and the method, preferably, comprises the steps of forming an aqueous solution of an organic polymeric material and a soluble phosphate or carbonate salt and causing the alkaline earth metal carbonate or phosphate inorganic particles to precipitate from said solution by the addition of an aqueous solution of a soluble salt, preferably a chloride, of the alkaline earth metal.

Claim 187. (New):A method as claimed in claim 175, wherein the inorganic particles comprise calcium carbonate and/or calcium phosphate and the organic polymeric material, preferably, is at least readily soluble in water at a temperature between 20 and 50°C within a period of 24 hours.

Claim 188. (New):A method as claimed in claim 175, wherein the polymeric material comprises:

(a) a polysaccharide and/or a protein; and/or,

(b) xanthan gum, dextran, acacia gum and/or egg albumen.

Claim 189. (New): A method as claimed in claim 184, wherein the solid particles employed to form the reticulated template are formed from latex.

Claim 190. (New): A method for preparing a pharmaceutical excipient, comprising the step of preparing a solid, reticulated matrix by a method as claimed in claim 175.

Claim 191. (New): A method for preparing a pharmaceutical excipient as claimed in claim 164, comprising heating a solid, reticulated matrix of organic polymeric material and inorganic particles to a sufficiently high temperature to both eliminate the organic polymeric material and cause the inorganic particles to fuse together into a second solid, reticulated matrix defining a plurality of pores with a mean width of up to 100μm.

Claim 192. (New): A method as claimed in claim 191, wherein:

(a) the organic polymeric material is eliminated and the organic particles caused to fuse by heating the solid, reticulated matrix to a temperature of about 800 to 1600°C; and/or

(b) the solid, reticulated matrix of organic polymeric material and inorganic particles is prepared, or preparable, by a method as claimed in any of claims 169-183 and/or is a matrix as defined in any of claims 147-157.

Claim 193. (New): A method as claimed in claim 191, wherein the solid, reticulated matrix is heated to a temperature of up to about 1100°C or about 1050°C, or to a temperature in excess of 1100°C, optionally, to a temperature within the range of about 1200 or 1250-1500°C.

Claim 194. (New): A pharmaceutical excipient comprising a solid, reticulated matrix prepared or preparable by a method as claimed in claim 175.

Claim 195. (New): A pharmaceutical product comprising a pharmaceutical excipient as claimed in claim 147, and a pharmaceutically active agent, optionally wherein the pharmaceutically active agent is particulate and solid.

Claim 196. (New): A pharmaceutical product comprising a pharmaceutical excipient as claimed in claim 150, and a pharmaceutically active agent, optionally wherein the pharmaceutically active agent is particulate and solid.

Claim 197. (New): A pharmaceutical product comprising a pharmaceutical excipient as claimed in claim 164, and a pharmaceutically active agent wherein, optionally wherein the pharmaceutically active agent is particulate and solid.

Claim 198. (New): A pharmaceutical product as claimed in claim 195, wherein:

(a) the pharmaceutically active agent is intimately associated with the excipient;

(b) the pharmaceutically active agent is located within the pores of the solid, reticulated matrix and/or coated onto the matrix or excipient;

(c) the pharmaceutically active agent lies within Class 2 in the FDA adopted Biopharmaceutical Classification System (BCS);

(d) the pharmaceutically active agent has an aqueous solubility of up to about 1 in 30 or 1 in 100 weight/volume, when measured at a temperature in the range of 15 to 25°C;

(e) the pharmaceutically active agent is crystalline;

(f) the pharmaceutically active agent is particulate, optionally crystalline, and the particles and/or crystals of pharmaceutically active agent have a mean width of about 10nm - 10μm, 10nm-5μm or less than about 1μm;

(g) said product comprises from about 1 to about 50% W/W pharmaceutically active agent;

(h) said product includes an additional pharmaceutically acceptable excipient and/or diluent; and/or,

(i) said product is in the form of an oral solid dosage form, preferably in the form of a powder, capsule or tablet.

Claim 199. (New):A pharmaceutical product as claimed in claim 196, wherein:

(a) the pharmaceutically active agent is intimately associated with the excipient;

(b) the pharmaceutically active agent is located within the pores of the solid, reticulated matrix and/or coated onto the matrix or excipient;

(c) the pharmaceutically active agent lies within Class 2 in the FDA adopted Biopharmaceutical Classification System (BCS);

(d) the pharmaceutically active agent has an aqueous solubility of up to about 1 in 30 or 1 in 100 weight/volume, when measured at a temperature in the range of 15 to 25°C;

(e) the pharmaceutically active agent is crystalline;

(f) the pharmaceutically active agent is particulate, optionally crystalline, and the particles and/or crystals of pharmaceutically active agent have a mean width of about 10nm - 10μm, 10nm-5μm or less than about 1μm;

(g) said product comprises from about 1 to about 50% W/W pharmaceutically active agent;

(h) said product includes an additional pharmaceutically acceptable excipient and/or diluent; and/or,

(i) said product is in the form of an oral solid dosage form, preferably in the form of a powder, capsule or tablet.

Claim 200. (New):A pharmaceutical product as claimed in claim 197, wherein:

(a) the pharmaceutically active agent is intimately associated with the excipient;

(b) the pharmaceutically active agent is located within the pores of the solid, reticulated matrix and/or coated onto the matrix or excipient;

(c) the pharmaceutically active agent lies within Class 2 in the FDA adopted Biopharmaceutical Classification System (BCS);

(d) the pharmaceutically active agent has an aqueous solubility of up to about 1 in 30 or 1 in 100 weight/volume, when measured at a temperature in the range of 15 to

25°C;

(e) the pharmaceutically active agent is crystalline;

(f) the pharmaceutically active agent is particulate, optionally crystalline, and the particles and/or crystals of pharmaceutically active agent have a mean width of about 10nm - 10μm, 10nm-5μm or less than about 1μm;

(g) said product comprises from about 1 to about 50% W/W pharmaceutically active agent;

(h) said product includes an additional pharmaceutically acceptable excipient and/or diluent; and/or,

(i) said product is in the form of an oral solid dosage form, preferably in the form of a powder, capsule or tablet.